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CENTRAL FAX CENTERIn re: Appln No. 09/707,685  
Amendment dated October 25, 2005  
Reply to Office action of April 25, 2005

OCT 25 2005

Cust. No. 29,335  
Atty Docket: 6006-015**Remarks**

The pending claims stand rejected on the following basis:

1. Claims 39-53 are rejected under 35 U.S.C. §102(e) as being anticipated by Whitcher, et al;
2. Claims 39-40, 42, 46-53;
3. Claim 45 is rejected under 35 U.S.C. §112, second paragraph.

**Amendment to Claim 45 Traverses §112, second paragraph Rejection**

Applicant has amended Claim 45 to include the process parameter of deposition rate as being the controlled process parameter. Applicant submits that the present amended Claim 45 traverses the rejection under 35 U.S.C. §112, second paragraph.

**Whitcher, et al. (U.S. Publication No. US 2003/0018381 A1) Fails to Anticipate the Claimed Invention.**

Applicant has amended independent claims 39 and 47 by deleting the limitation that grain size is controlled. Amended Claims 39-53 and new Claims 67- 74 are each directed to controlling vacuum deposition process parameters to control formation of chemical or intra- and inter-grannular precipitates. The Examiner implicitly acknowledges that the Whitcher reference is devoid of any teaching, express or implied, that it is known to control deposition process parameters in such a way as to control formation of inter- or intra-granular precipitates in the deposited film. Rather, the Examiner relies upon the doctrine of inherency in asserting that formation of chemical or intra and inter-granular precipitates in the bulk material is inherently controlled "since Whitcher discloses control of the grain size and boundaries and of the overall crystal structure of the metal; also, because Whitcher discloses selection of a temperature and pressure deposition, inherently the precipitates are being controlled, since amount and size of the grain/precipitates is dependent upon temp and pressure, upon selection of a temperature and pressure, one has controlled the crystal structure outcome of the metal...." (OA 4/25/2005, p. 4).

In re: Appln No. 09/707,685  
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Atty Docket: 6006-015

The Examiner's inherency argument is, however, made without any reference to any supporting references which teach or suggest that control over or selection of deposition temperature and pressure controls formation of chemical and inter- and intra-granular precipitates. MPEP §2112 clearly requires the Examiner to satisfy a burden of proof supporting the inherency argument. Specifically, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) [Emphasis added]. An "invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004)

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did

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Cust. No. 29,335  
Atty Docket: 6006-015

not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Here, while appearing to present a reasoned position, supported by Paragraphs 0035, 0036 and 0037 cited as purportedly teaching process conditions for vacuum deposition of a stent forming metal, and Paragraphs 011, 0028, 0038, 0042 and 0043 cited as purportedly teaching that such process conditions control grain size/crystal structure, the Examiner's position is based upon a faulty reading of the reference and subsequent deduction and supposition based upon such faulty reading. Thus, the Examiner's conclusion of inherency fails to meet the requisite burden of proof imposed by MPEP §2112.

Specifically, with respect to cited Paragraphs 0035, 0036 and 0037, these paragraphs merely recited known background information concerning evaporation processes, sputtering processes and ion-beam assisted deposition, respectively. Applicants', of course, acknowledge that these processes necessarily are conducted at a pre-selected temperature and a pre-selected chamber pressure. The issue presented by the pending claims is not merely whether a vacuum deposition process is conducted at a pre-selected temperature and a pre-selected chamber pressure, but that these in combination with others, are selected to control the formation of chemical and inter and intra-granular precipitates.

Whichever Paragraphs 0011, 0028, 0042 and 0043 each either merely recite the desirability of certain crystallographic structures as being either amorphous, nanocrystalline or monocrystalline structure (Paragraph 0011); that composition, thickness, surface roughness and microstructure may be controlled to form medical with desired compositions, mechanical properties and geometries (Paragraph 0028); that impurities may be removed and particular isotopes may be filtered to affect the crystalline structure and permit more ready formation of single crystal or monocrystalline materials (Paragraph 0038); that grain size may be reduced to between 1-100 nanometers (Paragraph 0042) and that the orientation of the nanometer sized grains can be controlled to yield an orderly grain structure with a similar crystal orientation (Paragraph 0043).

In re: Appln No. 09/707,685  
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Cust. No. 29,335  
Atty Docket: 6006-015

It will be noted that chemical and inter- and intra-granular precipitates are not mentioned in the foregoing litany of desirable results from the Whitcher disclosure. Paragraph 0038 obliquely references removing impurities and filtering particular isotopes to affect formation of single crystal or monocrystalline materials. Of particular curiosity is the references emphasis on single or monocrystalline materials. An example of a single or monocrystalline material is Si, GaAs or GaN, which are employed in semiconductor manufacture. Metals used in forming medical devices are polycrystalline materials and are not single or monocrystalline materials nor are they amorphous materials. Thus, the statement in Paragraph 0038 that "medical devices formed as a monocrystalline, monoisotopic material are useful with the present invention" requires that the material be "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit" (See, e.g., [http://www.nhm.ac.uk/hosted\\_sites/ina/terminology/7crystallography.htm](http://www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm)). Thus, single crystal and monocrystalline are synonymous terms.

However, Paragraph 0043, also relied upon by the examiner controverts that single crystal or monocrystalline nanometer grain structures may be deposited during deposition by stating "Such nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques can be used to form nanometer sized crystals." [Emphasis added]. The, the reference itself, clearly controverts that crystalline materials are deposited (in that it admits that amorphous materials are deposited), then the crystalline structure is formed by the "aging techniques" described in Paragraph 0041). Thus, to the extent that Whitcher teaches vacuum deposition of medical device forming films, such films are deposited as amorphous, non-crystalline films, which are treated post-deposition, to convert the amorphous film to a crystalline material, which, necessarily would have to be polycrystalline not monocrystalline as suggested by the reference.

In fact, therefore, Whitcher fails to teach control over the grain structure by controlling or selecting deposition process parameters. Rather, the express teaching of Whitcher is that the medical devices are deposited with an amorphous (non-crystalline) morphology, which is subsequently "treated or aged under conditions .... to form a monocrystalline metallic structure." Paragraph 0041. Thus, for the Examiner to argue that even grain size (much less chemical or

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Cust. No. 29,335  
Atty Docket: 6006-015

inter and intra-granular precipitates) is controlled during the deposition process is diametrically at odds with the express disclosure of the reference.

Thus, in view of the foregoing remarks and the amended claims, Applicants respectfully submit that the Examiner has failed to satisfy the burden of proof necessary to establish inherent disclosure in the Whitcher reference, and solicits the Examiner's reconsideration of the reliance upon the Whitcher, et al reference and withdrawal of the rejection under 35 U.S.C. §102(e).

**Johnson et al. (US 6,533,905 B2) Fails to Anticipate the Pending Claims**

The Examiner cites Johnson, et al as teaching a vacuum deposited nickel-titanium film (referencing Col. 4, lines 52-53; Col. 5, lines 19-20). The Examiner asserts, without citing to the reference, that Johnson teaches that it is known that process conditions teach control of grain size or formation of chemical and inter and intra-granular precipitates in the bulk material. In fact, the express teaching of the Johnson reference teaches that after the sputter deposited film is formed, it is annealed. (Col. 5, lines 48-60). This annealing step is required specifically because the as deposited film is amorphous (precisely like in Whitcher) and not crystalline. Annealing is required to form the crystalline morphology of the material. See, e.g., U.S. Patent Application No. 2004/0191556, Paragraph 0005, which is not prior art to the present application, but corroborates that after sputter depositing NiTi, annealing was required to change the amorphous morphology of the deposited film to a crystalline microstructure.

The post-deposition annealing step, such as that required by the Johnson reference, is further required to drive out inter- and intra-granular precipitates in the bulk material which are present in the as-deposited film. See, e.g., U.S. Patent Application No. 2003/0059640, commonly assigned to the assignee of this application. Thus, by virtue of Johnson teaching the necessity of the annealing step, one of skill in the art, would understand 1) that the as-deposited film is amorphous and not crystalline in morphology and 2) that chemical or inter- or intra-granular precipitates exist in the as-deposited film. Therefore, contrary to the Examiner's assertion, the deposition conditions are **NOT** selected or controlled in a manner to control formation of chemical, inter- or intra-granular precipitates.

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Cust. No. 29,335  
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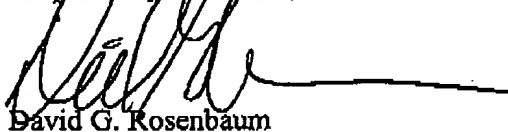
Thus, in view of the foregoing amendments and remarks, Applicants respectfully solicit the Examiner's reconsideration of the reliance upon the Johnson, et al reference and withdrawal of the rejection under 35 U.S.C. §102(e).

**Summary**

Applicants have amended the claims to positively recite the method step of selecting vacuum deposition process parameters to control formation of chemical and inter and intra-granular precipitates. The Examiner's position that this is merely reciting a condition misapprehends that the claim affirmatively claims the step of selecting process parameters to control the formation or occurrence of that "condition". Neither Whitcher nor Johnson anticipate, expressly, impliedly or by inherency the step of selecting process parameters to control formation of chemical or inter- and intra-granular precipitates.

While Applicants do not believe any fees, aside from the Extension fee, are required with this response, the Director is hereby authorized to deduct any other fee required for this response from deposit account 18-2000.

Respectfully submitted,



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